Registration Decision RD2012-24

Trichoderma virens strain G-41

(publié aussi en français)

5 July 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2012-24E (print version)
H113-25/2012-24E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2012

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Registration Decision for *Trichoderma virens* strain G-41

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of G-41 Technical and RootShield Plus Wettable Powder, containing the technical grade active ingredients *Trichoderma virens* strain G-41 and *Trichoderma hazianum* Rifai strain KRL-AG2, to suppress certain *Phytophthora* species that cause root rot on outdoor container-grown ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Trichoderma virens* strain G-41 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-06. This decision is consistent with the proposed registration decision stated in PRD2012-06.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Trichoderma virens* strain G-41?

Trichoderma virens strain G-41 a naturally occurring soil fungus that was isolated from soils in North America. It occupies a special niche on the roots of plants but can be found on decaying wood and vegetable matter. *Trichoderma virens* strain G-41 is used as a microbial pest control agent (MPCA) in G-41 Technical, and the associated end-use product, RootShield Plus Wettable Powder. RootShield Plus Wettable Powder is a commercial fungicide which contains live spores of the MPCA, and is proposed for use to protect the roots of outdoor container-grown ornamentals/nursery plants against root rot fungal pathogens (for example, *Phytophthora parasitica* and *Phytophthora cinnamomi*).

When applied to soil, the MPCA actively grows on the developing plant roots. There appears to be several methods of antagonism towards pathogens. Systemic resistance appears to be induced in response to the production of various fungal metabolites, particularly gliotoxin. Mycoparasitism of fungal pathogens and competition for resources also play a role in antibiosis of the fungal pathogens.

In addition to *Trichoderma virens* strain G-41, the end-use product also contains the registered MPCA *Trichoderma harzianum* strain KRL-AG2 (Registration number 27114; 5.0%; 1.0×10^7 CFU/g dry wt).

Health Considerations

Can Approved Uses of *Trichoderma virens* strain G-41 Affect Human Health?

***Trichoderma virens* strain G-41 is unlikely to affect your health when RootShield Plus Wettable Powder is used according to the label directions.**

Exposure to *Trichoderma virens* strain G-41 may occur during handling of RootShield Plus Wettable Powder.

When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the levels to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns.

When *Trichoderma virens* strain G-41 was tested on laboratory animals, there were no signs that it caused any toxicity or disease.

The end-use product, RootShield Plus Wettable Powder was not a dermal irritant, but was mildly irritating to the eyes. Workers primarily exposed to the product will be required to wear standard personal protective equipment including eye goggles to reduce the potential for dermal and ocular exposure.

Like all microbial pest control agents, *Trichoderma virens* strain G-41 contains substances that can cause allergic reactions in people who are repeatedly exposed to it at high concentrations. G-41 Technical and RootShield Plus Wettable Powder also contain the allergens, wheat and sulphites. However, allergic reactions can be avoided if commercial applicators follow label recommendations to minimize or limit exposure to RootShield Plus Wettable Powder.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

As there are no direct applications to food, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals. Consequently, the establishment of an MRL is not required for *Trichoderma virens* strain G-41. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling RootShield Plus Wettable Powder

Occupational risks are not of concern when RootShield Plus Wettable Powder is used according to label directions, which include protective measures.

Workers using RootShield Plus Wettable Powder can come into direct contact with *Trichoderma virens* strain G-41 on the skin, by inhalation, or in the eyes. For this reason, the label will specify that users exposed to RootShield Plus Wettable Powder must wear waterproof gloves, long-sleeved shirts, long pants, and shoes plus socks, eye goggles, and a dust/mist filtering NIOSH approved respirator/mask (with any N-95, P-95, R-95 or HE filter) until mists have settled and during clean-up and repair activities. After application of RootShield Plus Wettable Powder, workers will be cautioned to avoid skin contact with treated soil/potting mix.

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When RootShield Plus Wettable Powder Is Introduced Into the Environment?

Environmental risks are not of concern.

Following application, *Trichoderma virens* strain G-41 is likely to survive in the environment under favourable environmental conditions (in other words, temperature, humidity) but over time populations of *Trichoderma virens* strain G-41 are expected to return to natural background levels.

There are no published reports of disease associated with *Trichoderma virens* strain G-41 in birds, wild mammals, fish, insects or plants, except for the intended pest.

Also, minimal exposure to non-target organisms is anticipated from the proposed use of RootShield Plus Wettable Powder as a soil drench to control root rot in outdoor container-grown ornamentals.

Value Considerations

What Is the Value of RootShield Plus Wettable Powder?

RootShield Plus Wettable Powder contains *Trichoderma virens* strain G-41 and *Trichoderma harzianum* Rifai strain KRL-AG2, which is currently registered as RootShield to suppress root pathogens on outdoor container-grown ornamentals.

Trichoderma virens G-41 has been combined with *Trichoderma harzianum* KRL-AG2 to suppress *Phytophthora* root pathogens on ornamental crops.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of RootShield Plus Wettable Powder to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Although the potential for toxicity is low in individuals exposed to *Trichoderma virens* strain G-41, sensitization may occur upon repeated exposure to high concentrations of the product. A label statement warning users that the product is a potential sensitizer is required. G-41 Technical and RootShield Plus Wettable Powder contain the allergen, wheat and RootShield Plus Wettable Powder also contains the allergen, sulphites. Consequently, label statements warning users as to the presence of these allergens are required on the labels for G-41 Technical and RootShield Plus Wettable Powder. To minimize exposure to mists generated while handling or applying RootShield Plus Wettable Powder, applicators, mixer/loaders, and handlers will be required to wear personal protective equipment, including a long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, eye goggles, and a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products until mists have settled and during all clean-up/repair activities. After application, workers will be cautioned to avoid skin contact with treated soil/potting mix. A label statement will also warn users that RootShield Plus Wettable Powder is a mild eye irritant.

Environment

As a general precaution, the label prohibits the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The label also directs users to avoid contaminating surface water by disposal of equipment wash waters.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-06, *Trichoderma virens* strain G-41) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.